Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	
v.	**Criminal No: 09-CR-10330-GAO**
(1) STRYKER BIOTECH, LLC, **(2) MARK PHILIP,** **(3) WILLIAM HEPPNER,** **(4) DAVID ARD and** **(5) JEFFREY WHITAKER,**	
Defendants.	

DEFENDANTS' DISCLOSURE OF ANTICIPATED EXPERT TESTIMONY

DR. JONATHAN N. GRAUER

Pursuant to Fed. R. Crim. P. 16(b)(1)(C)(i), Defendants hereby disclose a written summary of the anticipated testimony of Jonathan N. Grauer, M.D., who may be called to testify during the course of the Defendants' case at trial. Dr. Grauer may offer other and further expert (fact and/or opinion) testimony in response to issues that may be raised hereafter or based on additional discovery provided by the Government, and its fact or expert witnesses, before or during trial of this matter. Correspondingly, Defendants reserve the right to supplement this disclosure as provided under Rule 16(c).

Dr. Grauer is an experienced orthopedic spine surgeon, currently serving as Associate Professor in the Department of Orthopaedics and Rehabilitation at Yale University School of Medicine. Dr. Grauer served as a pre-clinical investigator on the OP-1 device and as a member of Stryker Biotech's OP-1 expert panel before the United States Food and Drug Administration

("FDA"). Dr. Grauer is a graduate of Tufts University and Yale School of Medicine. A copy of his *curriculum vitae* is attached.

If called, Dr. Grauer is expected to describe the potential risk and benefits underlying spinal fusion surgeries, generally; the predictably "higher-risk" profile of the typical revision fusion patient; the medical procedure such surgeries entail; the biological theory and science behind the use of bone morphogenetic proteins ("BMPs") in spinal surgery; and the biological theory and science behind the use of bone graft substitutes, sometimes known as bone void fillers ("BVFs"), in spinal surgery. The basis for this testimony is Dr. Grauer's education, training, clinical experience, duties as a professor of orthopedic surgery, and the scientific research and data review he has conducted on OP-1 and other BMPs.

Dr. Grauer is further expected to testify that "mixing" has long been standard practice in spinal surgery, particularly in the preparation of bone graft, as iliac crest, bone marrow aspirate, and BMPs all can be mixed with local bone, cadaveric bone, blood, saline, BVFs, or certain ceramic products. Dr. Grauer is expected to testify as to the substantial difficulties (*e.g.*, greater pain and time in recuperation; greater risk of blood loss; greater risk of infection and fracture due to weakening) presented in standard iliac crest graft procedure, and thus, how use of BMPs represent a significant advancement in spinal fusion surgery.

Dr. Grauer will also testify that as the primary orthopedic surgeon during a case, he decides how a surgical procedure will take place, including whether to employ one or more medical devices; that if more than one device or product are to be combined or mixed, he decides in what manner and in what combination such products should be mixed; and that because all patients are different, and no procedures present precisely the same circumstances, determination of the proportion and volume of such combination, together with the manner and location of

placement, is a matter of surgical technique left to the judgment and discretion of the primary surgeon.

Dr. Grauer will also describe, generally, how posterolateral lumbar fusion ("PLF") surgery is arranged, prepared for, and conducted; how the operating room for spinal fusion surgery is typically configured, together with a description of the number and members of the surgical team and all others routinely present for the surgery; and what role each such individual (including medical device industry sales representatives) plays in the operating room. Dr. Grauer will further describe his understanding of how all products to be made available, and those ultimately used, in the course of a given spinal fusion surgery are identified and logged on his hospital's pre-surgery booking sheets, operating room records, and in a post-surgery operative report.

Relatedly, Dr. Grauer will testify that as with all physicians, he is bound to exercise independent medical judgment in the best interests of his patient; that his judgment in the course of preparing for spinal surgery routinely leads him to use BMPs, and that he occasionally uses BMPs in combination with a BVF, or in a non-FDA-approved or otherwise "off-label" fashion; that the combination of a BMP and BVF typically is not expected to alter the action of the BMP or otherwise result in a biologically unique "third product"; and that orthopedic "off-label" practice, including the mixing of osteogenic (*e.g.*, BMP) and osteoconductive (*e.g.*, BVF) materials, has become widespread in spinal fusion surgery. The basis for the above testimony is Dr. Grauer's own research; his years of experience as a orthopedic surgeon, and in particular, his knowledge of the characteristics of the spinal fusion patient; and his familiarity with the BMP and BVF products available for use in such surgeries.

In addition, Dr. Grauer will testify that he familiarizes himself with adverse events in his field through regular review of medical literature, participation in major orthopedic conferences, and discussions with his peers and colleagues; that he is not aware of any consistently reported serious safety concerns or elevated levels of adverse events associated with the use of OP-1 products; that post-surgical inflammation, wound drainage, and infection are all risks common to all forms of orthopedic surgery, whether using OP-1 or not, and that surgical technique can affect rates of infection; that product migration is a risk associated with any type of spinal bone graft, whether using OP-1 or not, and that some product migration of bone graft materials following a spinal fusion is not inherently of clinical concern; and that none of the incidences of possibly OP-1-related heterotopic bone growth of which he was aware was of lasting clinical concern. The bases for these opinions are Dr. Grauer's clinical experience; his ongoing review of medical literature in the field; his discussions with colleagues at Yale, the North American Spine Society, the Lumbar Spine Society, and the Spine Study Group; and his review of OP-1 clinical data prior to service as a member of the Stryker Biotech expert panel before the FDA.

Finally, Dr. Grauer is expected to testify regarding the nature of the professional relationship between orthopedic surgeons and sales representatives for medical device companies. He will describe the presence of medical product sales representatives in the operating room, at the request of the primary surgeon, as a matter of course; as well as the ways in which sales representatives routinely assist and interact with the surgical team. Dr. Grauer will also testify that he primarily relies on his own research and experience for information regarding the FDA-approved status of products, clinical studies conducted on products, or on adverse events related to certain surgical products; and that he chooses what products to use based on his professional judgment as to the best interest of his patients. He will further testify

that if a sales representative were to describe a Humanitarian Device Exemption ("HDE") approval as a "steppingstone" to a Premarket Approval ("PMA"), Dr. Grauer would not consider such statement inaccurate. Dr. Grauer's testimony in this regard is based on his education, training, extensive scientific research and publications, and his experience as a practicing orthopedic surgeon specializing in spine surgery and professor of orthopedic surgery.

Respectfully submitted,

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Dated: November 9, 2010